REMARKS

The Office Action mailed January 23, 2001, has been received and reviewed. Claims 30-50 are pending in this application. Claim 30 is amended to recite biological conduits. Support for this amendment is found, for example, at page 2, line 17 and page 3, line 15.

Claims 31-50 are new. Support for claims 31-50 is found throughout the specification. For example, support for claims 31-33, 38-41, 47-50 is found at, but not limited to, page 7, lines 3-19. Support for claim 34 is found at, but not limited to, page 5, lines 16-19 and page 8, lines 24-26 (claim 5 as originally filed). Support for claim 35 is found at, but not limited to, page 3, lines 10-12, page 5, lines 24-28 and page 6, lines 8-17. Support for claim 36 is found at page 9, lines 18-19 (claim 12 as originally filed). Support for claim 37 is found at, but not limited to, page 6, lines 1-7. Support for claims 42-46 is found at, but not limited to, page 3, line 25 to page 4, line 3, and page 5, line 24 to page 7, line 2.

Double Patenting Rejection

Claim 30 was rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 24 of U.S. Patent No. 6,110,201. This rejection is respectfully traversed. If, however, this rejection is maintained and upon an indication of otherwise allowable subject matter, Applicants will provide a terminal disclaimer solely to further prosecution of the above-identified application.

The 35 U.S.C. §103(a) Rejection

The Examiner rejected claim 30 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,500,014 to Quijano *et al.* (hereinafter "Quijano") in view of U.S. Patent No. 5,197,976 to Herweck *et al.* (hereinafter "Herweck"). Applicants respectfully traverse the rejection.

Claim 30, as amended herewith, is directed to a vascular prosthetic that includes at least two biological valvular conduits, where each of the biological conduits has an inflow end and an outflow end and a biological valve. The biological valvular conduits are joined adjacent

their inflow ends and upstream of each of the biological valves to form a single vascular prosthetic having an inflow end with a cross-sectional area larger than the cross-sectional area of any of the inflow ends of the biological valvular conduits.

Quijano teaches a biological valvular prosthesis defined by a chemically fixed biological derived conduit having at least one integrally formed tissue valve (Abstract). The valvular prosthesis can be used to form a tubular prosthesis having one or more valves that may be used to bypass a defective venous valve or replace a defective heart valve (col. 6, lines 45-56). In using the biological valvular conduit prosthesis in the reconstruction of the pulmonary artery, one or both of the vein segments at either side of the valve may be modified (col. 14, lines 57-59). Quijano teaches that the valvular prosthesis is formed from only a single conduit. Quijano fails to teach or suggest joining at least two valvular conduits adjacent to their inflow ends to form a single vascular prosthetic.

Herweck teaches a synthetic vascular graft having a plurality of tubular structures, each of which is manually separable from the others. Each of the tube structures is separable from the others over at least a portion of the axial extent of the exterior surface (Abstract). The tube structures are joined by a wall that allows them to be separated (col. 4, lines 25-26). The lumina of the plural tubular structures can for separate and distinct flowthrough paths along the entire longitudinal extent of the prosthesis, or, as noted by the Examiner, can join at one end to form a single lumen (col. 2, lines 39-42).

Significantly, the Herweck graft is synthetic, not biological. It is manufactured by paste forming and stretching, where paste forming by extrusion of PTFE is known (col. 5, lines 21-25). The tube structures can be formed using other paste-forming operations, for example, any of the available molding processes (col. 8, lines 5-8). Moreover, the Herweck graft contains no valve; it is simply a device containing plural synthetic conduits to direct fluid flow.

Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness. The cited documents, either alone or in combination, do not teach or suggest all the claim limitations. Furthermore, there is no suggestion or motivation to combine

the teachings of the cited documents, and the teachings of the cited documents fail to provide a reasonable expectation of success in making the claimed device.

Herweck teaches a graft having synthetic parallel tube structures (conduits) that are attached to one another over at least a portion of their longitudinal extent (col. 2, lines 19-23). It does not teach a device having plural *biological* conduits, nor a device having a *valve* of any sort, more particularly a biological valve. Quijano teaches a device having a single biological conduit housing a biological valve. Modification of the device taught in Quijano using the teachings of Herweck would yield a hybrid device having biological valves positioned within synthetic conduits. The presently claimed invention, on the other hand, is a vascular prosthetic having a plurality of biological conduits each having a biological valve housed therein. Thus, the cited documents, alone or in combination, thus do not teach the device as claimed.

Even if the combined teachings of the cited documents do teach all elements the claimed device, which Applicants dispute, there is no reasonable expectation of success. Neither Quijano nor Herweck teaches a method for joining biological conduits adjacent their inflow ends and upstream of their biological valves to form a single vascular prosthetic having an inflow end with a cross-sectional area larger than the cross-sectional area of any of the inflow ends of the biological valvular conduits, as recited in claim 30. The only joining method taught is that of Herweck, which is specific for *synthetic* grafts. The synthetic graft of Herweck is, as noted above, fabricated as a single unit. The tube structures of Herweck are formed together through the use of polymer molding processes. The methods taught by Herweck to make a branched synthetic graft are wholly inapplicable to making a prosthesis utilizing biological conduits. Attempting to process the biological vein segments of Quijano using the polymer molding processes taught by Herweck would destroy the biological vein segments. One skilled in the art would not reasonably believe that Quijano's biological vein segments could be successfully joined using Herweck's synthetic polymer molding processes. Clearly, the biological conduits of Quijano could not be joined to form the device of claim 30 without the benefit of Applicants' disclosure.

Finally, motivation to combine the cited documents to achieve the claimed invention is lacking. Quijano teaches modification of the prosthesis segment on either side of a single valved conduit (col. 14, lines 58-59). However, none of the medical applications reviewed in Quijano appear to require a vascular prosthesis with *multiple conduits*. There is, as a result, no motivation in Quijano to join together at least two valved conduits to form the claimed device. Likewise, although Herweck teaches vascular graphs having multiple tube structures, it does not teach or suggest any applications that would require the introduction of *valves* into the multiple conduit grafts. Moreover, to modify the device of Quijano using the teachings of Herweck would render the device of Quijano unsatisfactory for its intended purpose. Specifically, attempting to join the biological valvular prosthesis of Quijano in the manner taught by Herweck would render the valvular prosthesis inoperable for its intended purpose as the extrusion process taught by Herweck would destroy the biological material taught by Quijano. If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Thus, there is no suggestion or motivation to make the modification proposed by the Examiner.

Reconsideration and withdrawal of the rejection of claim 30 under 37 C.F.R. §103(a) as being unpatentable over Quijano in view of Herweck is, accordingly, respectfully requested.

Summary

It is respectfully submitted that claim 30 is in condition for allowance, and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives at the below-listed telephone number if it is believed that prosecution of this application may be assisted thereby.

CERTIFICATE UNDER 37 C.F.R. 1.10:

The undersigned hereby certifies that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR §1.10 on the date indicated below and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Gara Ladwig

"Express Mail" mailing label number:
EL 888271285 US
Date of Deposit: November 2, 2001

2 November 2001
Date

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APPENDIX A - SPECIFICATION/CLAIM AMENDMENTS
INCLUDING NOTATIONS TO INDICATE CHANGES MADE
Serial No.: 09/605,118
Docket No.: P-10220.01

Amendments to the following are indicated by underlining what has been added and bracketing what has been deleted.

In the Claims

For convenience, all pending claims are shown below.

30. (Amended) A vascular prosthetic[,] comprising:

at least two biological valvular conduits, each of said biological conduits having an inflow end and an outflow end and a biological valve housed therein;

wherein each of said biological valvular conduits is joined adjacent said inflow ends and upstream of each of said biological valves to form a single [vascular prosthetic having an] inflow end with a cross-sectional area larger than the cross-sectional area of any of the inflow ends of said biological valvular conduits.

31. (New) The vascular prosthetic of claim 30 wherein the single inflow end is suitable for attachment to a heart to receive blood from the right ventricle.

32. (New) The vascular prosthetic of claim 30 wherein the biological valvular conduits comprise first and second outflow ends, wherein at least one outflow end is suitable for attachment to a pulmonary trunk.

33. (New) The vascular prosthetic of claim 32 wherein the first and second outflow ends are suitable for attachment to first and second pulmonary arteries.

34. (New) The vascular prosthetic of claim 30 wherein the biological valve of each biological valvular conduit opens at pressures as low as about 1 mm Hg and remains sealably closed so as to withstand backflow pressures greater than about 200 mm Hg.

35. (New) The vascular prosthetic of claim 30 wherein the cross-sectional area of the inflow end of the vascular prosthetic is greater than about 22 millimeters.

36. (New) The vascular prosthetic of claim 30 wherein the cross-sectional area of the inflow end of the vascular prosthetic is greater than about 28 millimeters.

37. (New) The vascular prosthetic of claim 30 wherein the at least two biological valvular conduits are chemically fixed.

38. (New) The vascular prosthetic of claim 30 wherein a first axial seam joins the at least two biological valvular conduits adjacent their inflow ends and upstream of each of the biological valves to form the single inflow end of the vascular prosthetic.

39. (New) The vascular prosthetic of claim 30 wherein each of the biological valvular conduits is further joined adjacent their outflow ends and downstream of each of the biological valves to form a single outflow end of the vascular prosthetic.

40. (New) The vascular prosthetic of claim 39 wherein a second axial seam joins the at least two biological valvular conduits adjacent their outflow ends and downstream of each of the biological valves to form the single outflow end of the vascular prosthetic.

41. (New) The vascular prosthetic of claim 39 wherein the single inflow end is suitable for attachment to the right ventricle and the single outflow end is suitable for attachment to a pulmonary trunk.

42. (New) A method for making a vascular prosthetic comprising:

joining at least two biological valvular conduits to form a single inflow end having a cross-sectional area larger than a cross-sectional area of each of the at least two biological valvular conduits; and

chemically fixing the vascular prosthetic.

43. (New) The method of claim 42 further comprising removing the at least two biological valvular conduits from a quadruped.

44. (New) The method of claim 42 further comprising joining the at least two biological valvular conduits to form a single outflow end having a cross-sectional area larger than a cross-sectional area of each of the at least two biological valvular conduits.

45. (New) The method of claim 42 wherein joining at least two biological valvular conduits forms the single inflow end having a diameter greater than 22 millimeters.

46. (New) The method of claim 42 wherein joining at least two biological valvular conduits includes forming an angular section adjacent the inflow end of each biological valvular conduit, and joining the at least two biological valvular conduits along the angular section adjacent the inflow end of each biological valvular conduit.

47. (New) A method for using a vascular prosthetic comprising:

providing the vascular prosthetic formed from a first biological valvular conduit and a second biological valvular conduit, wherein the vascular prosthetic comprises a single inflow end having a cross-sectional area larger than a cross-sectional area of each of the first and second biological valvular conduits; and

implanting the vascular prosthetic in a patient.

48. (New) The method of claim 47 wherein implanting the vascular prosthetic comprises attaching the single inflow end of the vascular prosthetic to a right ventricle at or about a location of the inflow of the pulmonary trunk, and attaching an outflow end of the first biological valvular conduit and the second biological valvular conduit to one of a first pulmonary artery and a second pulmonary artery.

49. (New) The method of claim 47 wherein implanting the vascular prosthetic includes attaching the single inflow end of the vascular prosthetic to a right ventricle at or about a location of the inflow of the pulmonary trunk; and

attaching an outflow end of the first biological valvular conduit and the second biological valvular conduit to different locations of the pulmonary trunk.

50. (New) The method of claim 47 wherein the vascular prosthetic further comprises a single outflow end, and wherein implanting the vascular prosthetic comprises attaching the single inflow end of the vascular prosthetic to a right ventricle, and attaching the single outflow end to the pulmonary trunk.